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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,237	10/14/2003	Kenneth B. Stokes	P-3586.01 Continuation 3	4635

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
11/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/685,237	STOKES ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 36-46 objected to because of the following informalities: in claim 36, “an delivery means” should read "a delivery means,” and the “wherein” clause should be recited before the “a delivery means” clause to provide antecedent basis for “said supply of said genetic material, protein, or genetically engineered cells." Appropriate correction is required.

2. In claim 37, “implantable” should be deleted.

3. In claim 40, “bolus to” should read “bolus of.”

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 36-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over March et al. (US 5,840,059, hereinafter “March”) in view of Rogart (US 5,380,836, hereinafter “Rogart”).

6. In regards to claims 36-38, 41, 42, 44, and 45, March discloses the essential features of the claimed invention including a system comprising purified and isolated genetic material to a selected location in a patient’s heart (col. 6, lines 4-39) using an endocardial catheter means (col. 2, lines 49-62), but does not expressly disclose that the genetic material is selected from the group of recombinant sodium channel-

encoding RNA, DNA, or cells containing said DNA. Rogart teaches a method comprising introducing recombinant sodium channel encoding RNA and DNA into host cells using vectors similar to March's to provide the predictable result of conferring optimal biological activity (col. 5, lines 22-33). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide March's invention with a means for introducing recombinant sodium channel encoding RNA and DNA into host cells using vectors similar to March's to provide the predictable result of conferring optimal biological activity. Please note March's modified invention will produce increase conductivity, thus improving the ability to sense an increased cardiac signal.

7. In regards to claim 40, March's device is capable of delivering a bolus (col. 5, lines 37-40).

8. In regards to claims 39, 43, and 46, March's modified invention discloses the essential features of the claimed invention except for a hollow helical screw-in element, that the encoded sodium channel protein is hH1, or that the system further includes an electrode for detecting cardiac signals. It is well known in the art to provide hollow helical screw-in elements to provide the predictable result of rigidly holding a catheter to the heart surface; to provide recombinant cells with hH1 to provide the predictable result of electro-physiologically normal cells; and to provide similar systems comprising electrodes for detecting cardiac signals to provide the predictable results of verifying proper cardiac function. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify March's invention by

providing a hollow helical screw-in element to provide the predictable result of rigidly holding a catheter to the heart surface; providing recombinant cells with hH1 to provide the predictable result of electro-physiologically normal cells; and to provide electrodes for detecting cardiac signals to provide the predictable results of verifying proper cardiac function.

Response to Arguments

9. Applicant's arguments with respect to claims 36-46 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Krafte et al. (see attached "Notice of References Cited") is an example of recombinant cells expressing the hH1 gene for proper electrophysiology, King (US 5,103,821) is an example of providing an electrode for sensing cardiac signals in a similar system, and Mulier et al. (US 5,405,376) is an example of a catheter having a hollow helical screw-in element.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/

Examiner, Art Unit 3762

/Angela D Sykes/
Supervisory Patent Examiner, Art Unit 3762